DETAILED ACTION

Amendment after Non-final rejection filed on January 28, 2008 is acknowledged. As described in the previous office action, claims 11-19 are no longer present in the amendment. Claims 11-19 have been considered as cancelled claims, and are reflected as such. Therefore, Claims 1-10 are pending in this application. Applicant elected Group I (claims 1-10) in the reply filed on 4/12/2007. Because applicant die not distinctly and specifically point out the supposed errors in the restriction requirement, the election had been treated as an election without traverse. Claims 1-10 are examined on the merits in this office action.

Julie Ha is the Examiner on record.

Sequence Compliance

1. Sequence listing filed on November 8, 2007 is acknowledged.

Withdrawn Objections and Rejections

2. Objection to the abstract is hereby withdrawn due to Applicant's amendment to the abstract.

3. Objection to claim 10 is hereby withdrawn due to Applicant's amendment to the claim.

4. Rejection under 35 U.S.C. 112/101 is hereby withdrawn due to Applicant's amendment to the claims.

5. Rejection under 35 U.S.C. 112, second paragraph, as being indefinite is hereby withdrawn due to Applicant's amendment to the claims.

Maintained Objections and Rejections

Information Disclosure Statement

6. The Information Disclosure Statement filed June 8, 2006 has been considered. Non-Patent literature references must include a title. Citations C3, C4 and C14 should be updated to include titles.

Response to Applicant's Arguments

7. Applicant at page 7 of the "Remarks" page filed on November 8, 2007 has stated that new IDS with titles are being submitted.

8. The Examiner could not find the new IDS filed either November 8, 2007 or January 28, 2008. Applicant is requested to update the IDS to include the titles.

35 U.S.C. 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-10 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Block (WO 02/43746).

Block teaches VIP, a 28 amino acid peptide consisting of HSDAVFTDNYTRLRKQMAVKKYLNSILN (SEQ ID NO: 1, p.3). Regarding claim 1, VIP comprises claimed SEQ ID NO:4. Regarding claims 2 and 3, VIP further comprises claimed SEQ ID NOS: 14 and 13. Regarding claim 4, Block teaches polypeptide having the sequence A_n-RKQMAVKKYL-B_m where A and B are independent and are any naturally occurring amino acid, and n and m are independent and have integer values ranging from 0-25 (page 7, lines 20-25). The polypeptide HSDAVFTDNYTRLRKQMAVKKYLNSILN (SEQ ID NO:1, p. 3) satisfies the limitation of claims 5 and 6. Regarding claim 7, Block teaches polypeptides identical to species i-vii and x (p. 7, line 25 through p. 8, line 10). Regarding claim 8, Block teaches that the polypeptides have the biological function of VIP or PACAP or any biologically active derivative, truncated for, analogue or fusion protein thereof (p. 9, line 20 through p. 10, line 19). Regarding claim 10, Block teaches formulating the peptides as an aerosol for inhalation (p. 16, line 9, p. 17, line 10). Block teaches that the compound is used in a pharmaceutical composition and formulations, comprising a pharmaceutically acceptable carrier, excipient or diluents (p. 12, lines 16-18).

11. The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome

either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Response to Applicant's Arguments

12. Applicant argues that "the Examiner's rejection is improperly based on examination of composition claims and not the method claims elected by the Applicant."

13. Applicant's arguments have been fully considered but have not been found persuasive because Block reference claims the same invention as the instant claims. The instant claims are drawn to a method of manufacturing, or a method of making the pharmaceutical formulation. Block claims are drawn to a use of a compound for the manufacture of a medicament (see claims 1-21 of Block reference). Block teaches pharmaceutical formulations of the same peptide. Thus, the reference disclose a method of manufacturing the peptide. Note that the instant claims do not recite a specific method by which the peptides are manufactured. Block reference meets all of the limitations of instant application.

14. Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al (EP 0 613 904, citation B8 on the IDS filed 6/8/2006).

Takahashi et al teach pharmaceutical composition comprising VIP and its analogues. Regarding claim 1, the polypeptide includes claimed SEQ ID NO:4 (Table 1,

line 1). Regarding claims 2 and 3, VIP further comprises claimed SEQ ID NOS: 14 and 13 (Table 1, line 1). Regarding claim 4, the polypeptide has the sequence A_n-RKQMAVKKYL-B_m, where A is HSDAVFWDNYT, B is NSILN, n is 10 and m is 5 (Table 1, line 1). Regarding claim 5, X=HSDAV, o=5, Y=NYTRL, and p=5. Regarding claim 6, q=0, X"=AV and r=2. Regarding claim 7, the polypeptide is identical to SEQ ID NO:1 (Table 1, line 1). Regarding claim 9, the polypeptides have the biological function of VIP (p. 3, lines 25-26). Regarding claim 10, the polypeptide may be formulated for inhalation (p. 4, line 33).The reference teaches the in vivo testing, thus implying the presence of pharmaceutically acceptable carrier (p. 4, lines 45-51).

15. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Noda et al (EP 0 663 406, citation B9 on the IDS filed 6/8/2006)

Noda et al teach pharmaceutical composition comprising VIP and its analogues. Regarding claim 1, the polypeptide includes claimed SEQ ID NO:4 (abstract, SEQ ID NO:2). Regarding claims 2 and 3, VIP further comprises claimed SEQ ID NOS: 14 and 13 (Table 1, line 1). Regarding claim 4, the polypeptide has the sequence An-RKQMAVKKYL-Bm where A is HSDAVFWDNYT, B is [N,K,Q]KAL[K,R]homoserine, n is 10 and m is 5 (Table 1, line 1). Regarding claim 5, X=HSDAV, o=5, Y=NYTRL and p=5. Regarding claim 6, q=0, X"=AV and r=2. Regarding claim 7, Nado et al teach a polypeptide that is identical to instant SEQ ID NO:1 (p. 3, SEQ ID NO:1). Regarding claim 8, the polypeptides are in a stabilized form (abstract). Regarding claim 9, the polypeptides have the biological function of VIP (p. 4, line 21). Regarding claim 10, the

polypeptide may be formulated for inhalation (p. 5, line 8). The reference teaches the method of making the polypeptide compounds (see Production Examples). Furthermore, the reference teaches in vivo administration of the compound, implying the presence of pharmaceutically acceptable carrier.

Response to Applicant's Arguments

16. Applicant argues that "[neither Block, Takahashi et al or Noda et al teach that the polypeptides can be used to treat patients suffering from a disease or disorder correlated directly or indirectly with sarcoidosis, Applicant asserts that the cited references do not anticipate the presently amended claims, by reason of inherency or otherwise." Furthermore, Applicant argues that "it is well accepted tenant of patent law that a new use of a known product, composition, or process is patentable subject matter if it is not obvious. Because Examiner acknowledges that the cited references do not teach the use of a peptide for treating patients suffering from a disease or disorder correlated directly or indirectly with sarcoidosis, the presently amended claims are patentable and not anticipated by references cited by Examiner in the outstanding office action."

17. Applicant's arguments have been fully considered but have not been found persuasive because the instant claims are drawn to a method of manufacturing the medicament and not to a method of treating a disease or a disorder correlated directly or indirectly with sarcoidosis. The cited references teach the polypeptides claimed in the instant claims. Furthermore the active method steps are missing from the instant claims,

and the reference teaches the method of manufacture of medicament and treating disease or disorder utilizing the medicament, the reference anticipates the instant claims. Therefore, the references anticipate all of the limitations of the instant claims. Furthermore, since the instant claims are drawn to a method of manufacturing a medicament, the patient populations would not be given any patentable weight, since the patient population or the disease or disorder would not play any role in a method of making the drugs. Additionally, the reference teaches the method of in vivo administration of the peptide composition. It is inherent that the pharmaceutical composition of the peptide must be made and present prior to the administration of the composition. Therefore, the cited references anticipate the instantly claimed invention.

Obvious Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

19. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

20. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-8 of copending Application No. 10/501,660. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one of ordinary skill in the art practiced the claims of instant application, one would necessarily achieve the invention of copending application.

22. Instant claims are drawn to a method for manufacturing a medicament comprising providing a peptide or a polypeptide comprising amino acid sequence RKQMAVKKYL and a pharmaceutically acceptable carrier.

23. The copending claims are drawn to a method for manufacturing a medicament for the treatment of a patient suffering from chronic obstructive pulmonary disease comprising providing a peptide or a polypeptide comprising amino acid sequence RKQMAVKKYL.

24. Since both sets of claims are drawn to a method of manufacture of a medicament using the identical polypeptides, one of ordinary skill in the art practicing one invention would achieve the invention of the copending application.

25. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-8 of copending Application No. 10/564,849. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one of ordinary skill in the art practiced the claimed invention of the instant application, one would necessarily achieve the invention of copending application, and vice versa.

27. The instant claims are drawn to a method for manufacturing a medicament for the treatment of a disease or a disorder correlated directly or indirectly with sarcoidosis comprising providing a peptide or a polypeptide comprising the amino acid sequence RKQMAVKKYL and a pharmaceutically acceptable carrier.

28. The copending claims are drawn to a method for inhibiting maturation of dendritic cells for the treatment of a pulmonary disease comprising administering to a patient a peptide or a polypeptide comprising the amino acid sequence RKQMAVKKYL.

29. Since the copending claims require the presence of the medicament having the sequence RKQMAVKKYL, and the instant claims are drawn to a method of manufacturing the medicament RKQMAVKKYL, the copending invention would necessarily require the method of manufacturing the medicament. Therefore, if one practiced the invention of the copending application, then one of ordinary skill in the art would necessarily lead to the invention of instant claims.

30. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Applicant's Arguments

31. Applicant argues that "in light of the present claim amendments, these provisional rejections are no longer proper."

32. Applicant's arguments have been fully considered but have not been found persuasive because the copending applications' claims are drawn to the same method claims. For example, for copending application 10/564,849 the claims are drawn to a method of inhibiting maturation of dendritic cells for the treatment of a pulmonary disease comprising administering the identical peptide of the instant claims to the patients. The copending application requires the "pharmaceutical composition of the peptide" and the instant claims are drawn to a method of manufacturing the peptide medicament. Since the medicament (the final medicament produced are identical) needs to be manufactured or present in order for administration to the patient, the inventions are the same. Therefore, if one of ordinary skill in the art practiced the method of manufacture of copending applications 10/501660 and 10/564,849, one would achieve the claimed invention of the instant application and vice versa.

New Rejection

35 U.S.C. 112, 2nd

33. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

34. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the

steps. See MPEP § 2172.01. The omitted steps are: active method steps to manufacture a medicament. For example, the only "method step" recited in the claims is the presence of amino acid sequences. However, the essential method step of making the medicament utilizing the amino acid sequence is missing.

Conclusion

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). No claims are allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654